



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

 ω ω ω ω ω ω ω ω ω

In re Application of:

Porter et al.

Serial No.: 10/764,294

Filed: 1/22/04

For: Detection of Endothelial

Dysfunction by Ultrasonic Imaging

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Group Art Unit: 3738

Confirmation No.:

Examiner:

Unknown

8260

CERTIFICATE OF MAILING 37 CFR 1.8

I hereby certify that this correspondence is being deposited on August 30, 2004 with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA22313-1450.

8-71-04

Donald Verplancken

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The Applicants, and the Attorney who signs below on the basis of the information supplied by the inventor and the information in his file, submit herewith patents, publications, or other information of which they are aware, which may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

While the information submitted in this Supplemental Information Disclosure Statement may be material pursuant to 37 CFR § 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is prior art for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97, this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made or that no other possibly material information as defined under 37 CFR § 1.56(a) exists.

1

The publications submitted herewith are set forth on the attached Forms PTO-SB8B.

If the sum of \$180.00 is due under 37 CFR § 1.17(p) pursuant to § 1.97, the Commissioner is hereby authorized to charge this fee, and any other fee necessary to make this submission timely, to the Deposit Account No. 20-0782 (UNMC/0014/DV).

Respectfully submitted,

Donald Verplancken Registration No. 33,217

MOSER, PATTERSON & SHERIDAN, L.L.P.

3040 Post Oak Blvd. Suite 1500

Houston, TX 77056

Telephone: (650) 330-2310 Facsimile: (650) 330-2314 Attorney for Applicant(s)

2

Please type a plus sign (+) inside this I	s Do
---	------

Examiner

PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Pap

Substitute for form 1449B/PTO

INFORMATION DISCLO STATEMENT BY APRI

(Use as many sheets as necessary)

of | Sheet 1 3

persons are required to respond to a collec-	tion of information unless it displays a valid OME	s control number
Application Number	10/764,294	
Filing Date	1/22/04	
First Named Inventor	Porter et al.	
Group Art Unit	3738	
Examiner Name	Unknown	
Attorney Docket Number	UNMC/0014	
Submission Date	August 31, 2004	

		NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published					
	1	PANZA, JULIO A. et al. "Abnormal Endothelium-Dependent Vascular Relaxation in Patients with Essential Hypertension." The New England Journal of Medicine. July 1990, 323(1): 22-27.					
	2	LEVINE, M.D., GLENN N. et al. "Cholesterol Reduction in Cardiovascular Disease." The New England Journal of Medicine. February 1995, 32(8): 512-521.					
	3	WIDLANSKY, MD, MICHAEL E. et al. "The Clinical Implications of Endothelial Dysfunction." <u>Journal of the American College of Cardiology.</u> October 2003, 42(7): 1149-1160.					
	4	ANDERSON, MD, TODD J. et al. "Close Relation of Endothelial Function in the Human Coronary and Peripheral Circulations." J. Am Coll. Cardiol. November 1995, 26(5): 1235-1241.					
	5	RIM, MD, SE-JOONG et al. "Decrease in Coronary Blood Flow Reserve During Hyperlipidemia is Secondary to an Increase in Blood Viscosity." <u>Circulation</u> . 2001, 104: 2704-2709.					
	6	BAYFIELD, MD, MATTHEW S. et al. "Deoxygenated Blood Minimizes Adherence of Sonicated Albumin Microbubbles During Cardioplegic Arrest and After Blood Reperfusion: Experimental and Clinical Observations with Myocardial Contrast Echocardiography." The Journal of Thoracic and Cardiovascular Surgery. June 1997, 113(6): 1100-1108.					
	7	OKUMURA, MD, KEN et al. "Effect of Acetycholine on the Highly Stenotic Coronary Artery: Difference Between the Constrictor Response of the Infarct-Related Coronary Artery and That of the Noninfarct-Related Artery." J. Am. Coll. Cardiol. March 1992, 19(4): 752-758.					
	8	VOGEL, MD, ROBERT A. et al. "Effect of a Sincle High-Fat Meal on Endothelial Function in Healthy Subjects." The American Journal of Cardiology. February 1997, 79: 350-354.					
	9	ANDERSON, TODD J. et al. "Endothelium-Dependent Coronary Vasomotion Relates to the Susceptibility of LDL to Oxidation in Humans." Circulation. May 1996, 93(9): 1647-1650.					
	10	CERIELLO, MD, ANTONIO et al. "Evidence for an Independent and Cumulative Effect of Postprandial Hypertriglyceridemia and Hyperglycemia on Endothelial Dysfunction and Oxidative Stress Generation - Effects of Short- and Long-term Simvastatin Treatment." <u>Circulation</u> . September 2002, 106: 1211-1218.					
	11	VINK, H. et al. "Evidence that cell surface charge reduction modifes capillary red cell velocity - flux relationships in hamster cremaster muscle." <u>Journal of Physiology</u> . 1995, 489.1: 193-201.					
	12	LUPATTELLI, MD, GRAZIANA et al. "Flow-mediated vasoactivity and circulating adhesion molecules in hypertriglyceridemia: Association with small, dense LDL cholesterol particles." <u>American Heart Journal</u> . September 2000, 140(3): 521-526.					
	13	JOHNSTONE, MD, MICHAEL T. et al. "Impaired Endothelium-Dependent Vasodilation in Patients with Insulin-Dependent Diabetes Mellitus." <u>Circulation</u> . December 1993, 88(6): 2510-2516.					

Date Considered *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this

form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2. 2

Sheet

PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

August 31, 2004

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. 10/764,294 **Application Number** Substitute for form 1449B/PTO Filing Date 1/22/04 INFORMATION DISCLOSURE First Named Inventor Porter et al. STATEMENT BY APPLICANT Group Art Unit 3738 **Examiner Name** Unknown (Use as many sheets as necessary) Attorney Docket Number UNMC/0014

Submission Date

3

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T,
	14	PORTER, MD, THOMAS R. et al. "Improved Myocardial Contrast with Second Harmonic Transient Ultrasound Response Imaging in Humans Using Intravenous Perfluorocarbon-Exposed Sonicated Dextrose Albumin." J. Amm. Coll. Cardiol. May 1996, 27(6): 1497-501.	
	15	JAYAWEERA, ANANDA R. et al. "In Vivo Myocardial Kinetics of Air-Filled Albumin Microbubbles During Myocardial Contrast Echocardiography - Comparison with Radiolabeled Red Blood Cells." <u>Circ. Res.</u> June 1994, 74(6):	
	16	PORTER, THOMAS R. et al. "Inhibition of Carotid Artery Neointimal Formation with Intravenous Microbubbles." <u>Ultrasound in Medicine and Biology</u> . 2001, 27(2): 259-265.	
	17	KELLER, MD, MARK W. et al. "Intraoperative Assessment of Regional Myocardial Perfusion Using Quantitative Myocardial Contrast Echocardiography: An Experimental Evaluation." J. Am Coll. Cardiol. November 1990, 16(5): 1267-79.	
	18	HACKMAN, MD, ANNE et al. "Levels of Soluble Cell Adhesion Molecules in Patients with Dyslipidemia." Circulation. April 1996, 93(7): 1334-1338.	
	19	CARLOS, TIMOTHY M. et al. "Leukocyte-Endothelial Adhesion Molecules." <u>Blood</u> . October 1994, 84(7): 2068-2101.	
,	20	CHRISTIANSEN, MB, ChB, JONATHAN P. et al. "Noninvasive Imaging of Myocardial Reperfusion Injury Using Leukocyte-Targeted Contrast Echocardiography." <u>Circulation</u> . April 2002, 105: 1764-1767.	
	21	DE MAN, FRITS H. et al. "Not Acute but Chronic Hypertriglyceridemia is Associated with Impaired Endothelium-Dependent Vasodilation - Reversal After Lipid-Lowering Therapy by Atorvastatin." Arterioscler. Thromb. Vasc. Biol. March 2000, 20: 744-750.	
	22	CELERMAJER, Ph.D., DAVID S. et al. "Passive Smoking and Impaired Endothelium-Dependent Arterial Dilatation in Healthy Young Adults." N. Engl. J. Med. January 1996, 34(3):150-4.	-
	23	ESKURZA, MD, IRATXE et al. "Pharmacologic Versus Flow-Mediated Assessments of Peripheral Vascular Endothelial Vasodilatory Function in Humans." <u>The American Journal of Cardiology</u> . November 2001, 88: 1067-1069.	
	24	RUIZ-ORTEGA, M. et al. "Fourth International Seminar on Cardiovascular Biology and Medicine: Part II." Hypertension. December 2001, 38: 1382-1387.	
	25	ABE, YASUNORI et al. "Soluble Cell Adhesion Molecules in Hypertriglyceridemia and Potential Significance on Monocyte Adhesion." <u>Arterioscler. Thromb. Vasc. Biol.</u> May 1998, 18: 723-731.	
	26	NEUNTEUFL, THOMAS et al. "Systemic endothelial dysfunction is related to the extent and severity of coronary artery disease." Atherosclerosis. 1997, 129: 111-118.	

Examiner **Date Considered**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including pathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449B/PTO				Application Number	10/764,294	
				Filing Date	1/22/04	
INFO	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			First Named Inventor	Porter et al.	
STAT				Group Art Unit	3738	
				Examiner Name	Unknown	
	(Use as many sheets as necessary)			Attorney Docket Number	UNMC/0014	
Sheet	3	of	3	Submission Date	August 31, 2004	フ

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	27	ANDERSON, MD, TODD J. et al. "Systemic Nature of Endothelial Dysfunction in Atherosclerosis." <u>Am. J. Cardiol</u> . February 1995, 75: 71B-74B.	
	28	CORRETTI, MARY C. et al. "Technical aspects of evaluating brachial artery vasodilatation using high-frequency ultrasound." <u>Am. J. Physiol.</u> 1995, 268: H1397-H1404.	
	29	LUNDMAN, MD, PIA et al. "Transient Tryglyceridemia Decreases Vascular Reactivity in Young, Healthy Men without Risk Factors for Coronary Heart Disease." <u>Circulation</u> . November 1997, 96(10): 3266-3268.	
	30	WELLER, PhD., GREGORY E.R. et al. "Ultrasound Imaging of Acute Cardiac Transplant Rejection with Microbubbles Targeted to Intercellular Adhesion Molecule-1." <u>Circulation</u> . July 3003, 108: 218-224.	
	1		
,,,,			
			_
			<u> </u>

Examiner

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.